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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,504

05/06/2004

Rafail Zubok

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,504	Applicant(s) ZUBOK ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-7, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pat. No. 6,113,637) in view of Branch et al. (US Pat. No. 6,174,311). Gill et al. discloses the following of the claim 1: an insertion plate, comprising: a base (central portion of element 76); a first mounting element (upper element 90) of the base; a second mounting element (lower element 90) of the base, wherein the first and second mounting elements cooperate to engage and orient first and second members of a two-piece intervertebral disc replacement device for simultaneous insertion into an intervertebral disc space of a spinal column; and a stem (74) with an insertion handle (72). The insertion plate further includes a ledge member (79). A portion of the intervertebral disc is removed from the spinal column (col. 8, lines 24-30); the first and second members are inserted into the disc space simultaneously; clips are available to allow the insert plate to remain coupled to the members while the members are being installed into the vertebral bones; and the insertion plate is removed from members after their insertion (col. 6, lines 49-67; col. 7, lines 30-53; col. 8, lines 24-55).

However, Gill et al. does not disclose the insertion plate including modular pieces, including the handle and the stem being connected by a bore and tapered shaft. Branch teaches an insertion tool that comprises modular pieces including a handle fitting into the bore of a stem

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in col. 10, line 39 through col. 11, line 57 for the purpose of giving the insertion tool a greater range of motion to make it easier to insert the implant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the insertion tool from modular pieces in order to give the insertion tool a greater range of motion and therefore, make it easier to insert the implant.

In addition it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the insertion device of Gill et al. into modular pieces, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. 168 USPQ 177, 179.

Claims 3, 4, 7, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. in view of Branch et al., as shown in claim 1, further in view of Michelson (US Pub. No. 2002/0004683). Gill et al., as modified by Branch et al., discloses the invention substantially as claimed, however, Gill et al. does not disclose the mounting elements and the intervertebral disc replacement device having flanges and holes for fasteners. Michelson teaches a spinal implant tool where the mounting elements and the intervertebral disc replacement device have flanges and holes for fasteners in paragraphs 0006-0013 and 0066-0075 for the purpose of better securing the intervertebral disc replacement device to the mounting elements. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mounting elements and the intervertebral disc replacement device with holes for fasteners in order to better secure the intervertebral disc replacement device to the mounting elements.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. in view of Branch et al., as shown in claim 15, further in view of Sanderson (U.S. Pat. No. 4,105,407). Gill et al., as modified by Branch et al., discloses the invention substantially as claimed, however, Gill et al. does not disclose the implant as being in a sterile package. Sanderson teaches a sterilization technique for medical devices in col. 2, lines 54-56 for the purpose of safeguarding the patient by preventing infection. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to make the implant part of a sterile assembly package to safeguard the patient by preventing infection.

Response to Arguments

Applicant's arguments filed 1/26/2009 have been fully considered but they are not persuasive. Upon further consideration of the claim language in the current application, the claims are directed towards only the insertion plate and not the combination of an insertion plate and an intervertebral disc replacement device. The amended language describes features of the disc replacement device, which has not been positively claimed because of the claims' functional language. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. It is respectfully suggested that the Applicant direct the claims towards a system or a kit comprising the insertion plate and the disc replacement device, so that the replacement device will be positively claimed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774